

Serial No. 10/602,215

PC 21501B

Please replace all prior claims in the application with the following:

Claim 1 (currently amended): A liquid pharmaceutical composition comprising a gamma-aminobutyric acid (GABA) analog selected from gabapentin and pregabalin, and one or more polyhydric alcohols, each containing 2 to 6 carbon atoms, and water, wherein the one or more polyhydric alcohols comprises about 25% to about 75% weight/volume 25 g to about 75 g per 100 mL of the composition and the composition has a pH of about 5.5 to about 7.0.

Claim 2 (previously presented): The composition according to claim 1, wherein the one or more polyhydric alcohols each contains 3 to 5 carbon atoms.

Claim 3 (currently amended): The composition according to claim 2 1, wherein the one or more polyhydric alcohols are selected from the group consisting of: glycerol, xylitol, sorbitol, mannitol, and a mixture of glycerol and xylitol mixtures thereof, and wherein the one or more polyhydric alcohols comprises about 40% to about 75% weight/volume 40 g to about 75 g per 100 mL of the composition.

Claim 4 (original): The composition according to claim 1, wherein the pH is about 6.0 to about 7.0.

Claim 5 (previously presented): The composition according to claim 1, comprising one or both of: a preservative and a flavor improver, wherein the flavor improver does not contain an aldehyde or keto functionality.

Claim 6 (currently amended): A method for preparing a liquid pharmaceutical composition comprising: adding one or more polyhydric alcohols, each containing 2 to 6 carbon atoms, to water to form a first solution; adding a gamma-aminobutyric acid analog selected from gabapentin and pregabalin to the first solution to form a second solution; and optionally adjusting the pH of the second solution to about 5.5 to about 7.0 to afford the liquid pharmaceutical composition, wherein the one or more polyhydric alcohols comprises about 25% to about 75% weight/volume 25 g to about 75 g per 100 mL of the composition.

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Claim 7 (currently amended): The method according to claim 6, wherein the one or more polyhydric alcohols ~~are~~ is a mixture of glycerol and xylitol.

Claim 8 (previously presented): The method according to claim 6, wherein the pH of the composition is about 6 to about 7.

Claim 9 (currently amended): A liquid pharmaceutical composition comprising a first component, the first component comprising a powder mixture of a gamma-aminobutyric acid (GABA) analog selected from gabapentin and pregabalin and one or more solid polyhydric alcohols, and a second component comprising a liquid base, wherein the first and second components are combined to afford the liquid pharmaceutical composition in which the one or more polyhydric alcohols comprises about ~~25% to about 75% weight/volume~~ 25 g to about 75 g per 100 mL of the composition.

Claim 10 (currently amended): A method for preparing a liquid pharmaceutical composition, the method comprising: mixing a gamma-aminobutyric acid (GABA) analog selected from gabapentin and pregabalin with a first solid polyhydric alcohol to afford a powder mixture; mixing a second polyhydric alcohol with a sweetener and a flavor in water to afford a liquid base; and adding the powder mixture to the liquid base to afford the liquid pharmaceutical composition, wherein the first and second polyhydric alcohols may be the same or different and together comprise about ~~25% to about 75% weight/volume~~ 25 g to about 75 g per 100 mL of the composition.

Claim 11 (currently amended): The method according to claim 10, wherein the GABA analog is gabapentin ~~or pregabalin~~.

Claim 12 (currently amended): The composition according to claim 1 or claim 9 wherein the GABA analog is gabapentin ~~or pregabalin~~.

Claim 13 (previously presented): The composition according to claim 1 or claim 9 wherein the composition has less than 0.5% by weight of the corresponding lactam of the GABA analog.

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Claim 14 (currently amended): A liquid pharmaceutical composition comprising gabapentin or pregabalin, water, and one or more polyhydric alcohols, each containing 2 to 6 carbon atoms, the composition having a pH of about 5.5 to about 7.0 and containing less than 0.5% weight/weight of gabapentin lactam or pregabalin lactam, respectively, after storage at 2°C to 10°C for 18 months to 2 years, wherein the one or more polyhydric alcohols comprises at least 25% weight/volume 25 g per 100 mL of the composition.

Claim 15 (canceled)

Claim 16 (currently amended): A method of treating a subject suffering from a cerebral disease, including epilepsy, faintness attacks, or hypokinesia; cranial trauma[[,]]; a neurodegenerative disorder[[,]]; depression[[,]]; mania[[,]]; bipolar disorder[[,]]; anxiety[[,]]; panic[[,]]; inflammation[[,]]; renal colic[[,]]; insomnia[[,]]; gastrointestinal damage[[,]]; incontinence[[,]]; migraine[[,]]; or pain, including neuropathic pain, muscular pain, or skeletal pain, the method comprising administering to the subject a therapeutically effective amount of the pharmaceutical composition according to claim 1 or claim 13.

Claim 17 (new): A liquid pharmaceutical composition comprising gabapentin, xylitol, glycerol, and water, wherein xylitol and glycerol together comprise at least 25 g per 100 mL of the composition and the composition has a pH of about 5.5 to about 7.0.

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